UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte EDMOND ROUSSEL, CHARLES LEGRAND, MARC LEGRAND, NATHALIE ROLAND and ALAIN OURRY

Appeal No. 2004-1555
Application No. 09/331,554

ON BRIEF

Before WINTERS, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 13-16, 19-21, 24-26, 29, and 30, all of the claims remaining. Claims 13-16 and 19 are representative and read as follows:

13. A composition for use as an absorbable dietary supplement for human and animal consumption comprising more than 10^9 cells/gram propionibacteria, said propionibacteria capable of releasing a physiologically significant amount of nitric oxide into the human and animal digestive tract for improving intestinal functions.

14. The composition according to Claim 13, wherein said propionibacteria, after cultivating for at least 72 hours in a Yeast Extract Lactate medium containing at least 550 µmol/liter of nitrate, is capable of releasing at least 5 µg of nitric oxide.

15. The composition according to Claim 13, wherein said composition is added to a food product selected from a list including cheese, sources of dietary fibre, fermented milk, dessert cream, cake, and tonic drink.

16. A dietary supplement according to Claim 13, wherein said supplement is a preparation of the form selected from the list of dehydrated, fermented liquid, and unfermented liquid preparations.

19. A composition for use as an absorbable dietary supplement for human and animal consumption comprising a sufficient quantity of propionibacteria and one or more selected from the group consisting of bifidobacteria and lactic acid bacteria, said composition capable of releasing a physiologically significant amount of nitric oxide into the human and animal digestive tract.

The examiner relies on the following references:

Hettinga et al. (Hettinga)	4,379,170	Apr. 05, 1983
Madec et al. (Madec)	5,573,947	Nov. 12, 1996

Claims 13-16, 19-21, 24-26, 29, and 30 stand rejected under 35 U.S.C. § 102(b) as anticipated by Hettinga.

Claims 13-16, 20, 21, and 24-26 stand rejected under 35 U.S.C. § 102(b) as anticipated by Madec.[1]

We affirm the rejection based on Hettinga and do not reach the rejection based on Madec.

Background

"[R]ecently . . . an impressive number of physiological functions have been attributed to nitric oxide and . . . the hypothesis was put forward that this gas might be involved extensively in functions as diverse as controlling arterial pressure, . . . platelet

[1] The examiner also included claim 28 in this ground of rejection, see the Supplemental Examiner's Answer, page 11, but claim 28 has been cancelled.

aggregation and neurotransmission, or controlling the motility of the digestive tract." Specification, page 1.

"[G]iven the abovementioned beneficial role of nitric oxide, it would be desirable to be able to increase this production in particular by using the natural route of food metabolism." Id., page 2. "[I]t has been possible to achieve the desired aim by observing that, surprisingly, bacteria of one specific type, the propionibacteria, are capable of producing nitric oxide." Id. "[P]ropionibacteria . . . produce the holes during the manufacture of the cheese known as 'emmental' which, after maturing, contains about 10^9 cells/g of propionibacteria." Id.

The specification provides working examples in which different strains of propionibacteria were cultured in vitro, under various conditions, and their nitric oxide production was measured. See pages 6-20. The specification also provides an example in which propionibacteria were administered to humans. See pages 25-26. Human volunteers were administered propionibacteria in the form of a "capsule containing 5×10^{10} propionibacteria obtained from a bank of strains used in the cheesemaking industry." Page 25. After two weeks, the transit time of radio-opaque markers through the digestive tract was measured and compared to results from before administration of the propionibacteria. The specification discloses that

> [t]his study revealed a significant deceleration in the transit time of the left colon . . .; the transit times of the right colon and of the rectosigmoid were not significantly modified by the ingestion of propionibacteria.
>
> This study thus proved that the ingestion of propionibacteria has an influence on intestinal motility; it can be assumed that these results are associated with the synthesis of nitric oxide by the propionibacteria.

Pages 25-26.

Discussion

1. Claim construction

Appellants have grouped the claims into five different groups. The following groups of claims stand or fall together: claims 13, 20, and 21; claim 14; claims 15, 25, and 26; claims 16 and 24; and claims 19, 29, and 30. Appeal Brief, page 12. We will consider claims 13, 14, 15, 16, and 19 to be representative of Appellants' groups.

We start with claim construction. See Key Pharms. Inc. v. Hercon Labs. Corp., 161 F.3d 709, 714, 48 USPQ2d 1911, 1915 (Fed. Cir. 1998) ("[A] determination of anticipation, as well as obviousness, involves two steps. First is construing the claim, . . . followed by, in the case of anticipation or obviousness, a comparison of the construed claim to the prior art.").

We give the claims their broadest reasonable interpretation consistent with the specification. In re Sneed, 710 F.2d 1544,1548, 218 USPQ 385, 388 (Fed. Cir. 1983) ("[I]n proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification and . . . claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art." (citation omitted)).

Claim 13 is directed to a composition "for use as an absorbable dietary supplement for human and animal consumption," comprising more than 10^9 cells/gram of propionibacteria. The claim also requires that the propionibacteria be "capable of releasing a physiologically significant amount of nitric oxide into the human and animal digestive tract for improving intestinal functions." The claimed composition therefore must comprise propionibacteria at a concentration of more than 10^9 cells per gram. It

must also be in a form suitable for ingestion, in order to be an "absorbable dietary supplement." Finally, the propionibacteria must be capable of releasing a "physiologically significant amount" of nitric oxide, which we construe, in accordance with the rest of the claim, to mean an amount that "improve[es] intestinal function." According to the specification, "improving intestinal function" includes, e.g., decreasing the transit time in the left colon.

Claim 14 depends from claim 13 and adds the limitation that the propionibacteria, "after cultivating for at least 72 hours in a Yeast Extract Lactate medium containing at least 550 µmol/liter of nitrate, [are] capable of releasing at least 5 µg of nitric oxide." This limitation is not as stringent as it at first appears. The requirement is simply to produce 5 µg of nitric oxide; not 5 µg per milliliter of culture, or 5 µg per ml per hour, or 5 µg per 10^9 cells. In addition, the claim requires that the 5 µg of nitric oxide be produced "after", not during, the 72 hours of culturing in YEL medium. Thus, we construe the claim to read on the same composition defined by claim 13, with the additional limitation that the propionibacteria, in any volume containing any number of cells, be able to produce at least 5 µg of nitric oxide when cultured in any medium for any period of time, so long as the nitric oxide production period is preceded by at least 72 hours of culturing in YEL medium.

Claim 15 depends from claim 13 and adds the limitation that the composition is "added to a food product selected from a list including cheese, sources of dietary fibre, fermented milk, dessert cream, cake, and tonic drink." Since the claim uses the term "including" to introduce the list of food products, we interpret those food products to be exemplary, but not limiting. Unlike "consisting of", "including" is an open-ended claim

term that does not exclude other elements that are not specifically named. See Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1344, 65 USPQ2d 1385, 1408 (Fed. Cir. 2003) ("'Comprising is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.' . . . The word 'include' means the same thing."). Thus, claim 15 reads on the composition of claim 13 added to any food product, including, but not limited to, those named in claim 15.

Claim 16 depends from claim 13 and adds the limitation that the composition is in the form of "dehydrated, fermented liquid, [or] unfermented liquid." We construe this claim to mean that the composition is either liquid (any liquid, since every liquid is either fermented or unfermented) or dehydrated (i.e., treated in such a way as to remove at least some water).

Claim 19 is an independent claim and is directed to a composition "for use as an absorbable dietary supplement for human and animal consumption," comprising "a sufficient quantity" of propionibacteria. In addition to propionibacteria, the claimed composition comprises bifidobacteria and/or lactic acid bacteria, and is "capable of releasing a physiologically significant amount of nitric oxide into the human and animal digestive tract." We interpret a "sufficient quantity" of propionibacteria to mean a quantity sufficient to release a physiologically significant amount of nitric oxide. Read in light of the rest of the claims and the specification, a "physiologically significant amount," in turn, means an amount that will result in improved intestinal function, e.g., decreased transit time in the left colon.

2. Anticipation

The examiner rejected all of the claims as anticipated by Hettinga.[2] The examiner pointed specifically to columns 9 and 10 of the reference, where Hettinga discloses a composition comprising more than 10^9 cells per gram of propionibacteria. Hettinga states that

> a Swiss or Emmental flavored cheese product was produced. The procedure of Example 1 was generally followed [(in relevant part, whole milk was separated into skim milk and cream, then the skim milk was concentrated by ultrafiltration and pasteurized)] except that the portion of skim milk concentrate was heat treated (180° F., 30 min.) . . . and 0.05% proline was added. The mixture was fermented with 80 ppm of Rhozyme P-11 (protease) and 6.6% inoculum of a 50/50 mixture of Propionibacteria P16 and P20 (G-broth, 6.2 X 10^9 cells per gram of P16, 1.2 X 10^9 cells per gram of P20) for 5 hours.

Column 9, lines 44-52 (emphasis added).

A claim is anticipated "if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). For example, "[i]n response to the PTO's asserted prima facie case the applicant may argue that the inference of lack of novelty was not properly drawn, for example if the PTO did not correctly apply or understand the subject matter of the reference, or if the PTO drew unwarranted conclusions therefrom." Id.

[22] The examiner also rejected claims 13-16, 20, 21, and 24-26 as anticipated by Madec. However, since we conclude that all of these claims are anticipated by Hettinga, we need not consider whether they are also anticipated by Madec.

See also In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977): "[I]t is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on."

We agree with the examiner that the products disclosed by Hettinga reasonably appear to anticipate claims 13-16 and 19.

A. Claim 13

Claim 13 is directed to an ingestible composition comprising more than 10^9 cells/gram of propionibacteria, where the propionibacteria produce sufficient nitric oxide to improve intestinal function. The specification's working example (pages 25-26) shows that strains of propionibacteria used in the cheesemaking industry have the property of producing nitric oxide. Hettinga discloses a composition comprising more than 10^9 cells/gram of propionibacteria; the propionibacteria reasonably appear to belong to strains used in cheesemaking, since that is what Hettinga is using them for; and the composition is added to skim milk to make cheese, and therefore reasonably appears to be an ingestible composition. Thus, Hettinga appears to anticipate claim 13.

B. Claim 14

Claim 14 adds to claim 13 the limitation that the propionibacteria are capable of producing 5 μg of nitric oxide after having been cultured under certain conditions for 72

hours. The claim does not limit the volume of culture, the number of cells, or the time required to produce the recited 5 µg of nitric oxide. Therefore, it is reasonable to conclude that the propionibacteria disclosed by Hettinga would be capable of producing 5 µg of nitric oxide, if cultured in sufficiently large quantities for a sufficient period of time. Thus, Hettinga reasonably appears to anticipate claim 14.

C. Claim 15

Claim 15 adds to claim 13 the limitation that the composition is added to a food product that can be, but is not necessarily, chosen from the recited list. Hettinga discloses that the propionibacteria inoculum is added to skim milk concentrate, which is reasonably appears to be a food product. Thus, Hettinga anticipates claim 15.

D. Claim 16

Claim 16 adds to claim 13 the limitation that the composition is either dehydrated or a liquid. Hettinga discloses that the propionibacteria inoculum has a "G-broth" base; a broth-based composition reasonably appears to be a liquid. Thus, Hettinga anticipates claim 16.

E. Claim 19

Claim 19 is directed to a propionibacteria-containing composition like that of claim 13, which also comprises bifidobacteria and/or lactic acid bacteria. Hettinga discloses the further addition of Lactobacillus bulgaricus to the skim milk/propionibacteria composition already discussed. See column 10, line 13. Lactobacillus bulgaricus reasonably appears to meet the claim limitation requiring the presence of "lactic acid bacteria." Thus, Hettinga anticipates claim 19.

For the reasons discussed above, we conclude that Hettinga reasonably appears to anticipate claims 13-16 and 19. The burden therefore shifts to Appellants to show that the claimed products differ from those in the prior art.

Appellants argue that Hettinga "in no way teaches or suggests, let alone expressly describes, that NO [nitric oxide] may be synthesized by propionibacteria or by any of the processes described therein." Appeal Brief, page 18.[3]

This argument is not persuasive. For the reasons discussed above, those skilled in the art would reasonably expect the prior art compositions to have the properties recited in the instant claims; it makes no difference whether Hettinga expressly described those properties. See In re Spada, 911 F.2d at 709, 15 USPQ2d at 1658 ("When the claimed compositions are not novel they are not rendered patentable by recitation of properties, whether or not these properties are shown or suggested in the prior art.").

Appellants also argue that Hettinga does not inherently describe the claimed compositions because it is not "necessary and inevitable that, in the disclosed cheese-making process, the propionibacteria release a physiologically significant amount of NO into a human or animal digestive tract." Appeal Brief, page 18.

This argument is also unpersuasive. The claim is not limited to a composition comprising propionibacteria that actually release a physiologically significant amount (or any amount, for that matter) of nitric oxide. The claim requires only that the propionibacteria in the composition be "capable of releasing" the recited amount of nitric

[3] "Appeal Brief" refers to the Amended Brief on Appeal, received Nov. 24, 2003.

oxide in the digestive tract. That limitation reasonably appears to be met by Hettinga. Hettinga discloses compositions comprising strains of propionibacteria used in cheesemaking. The instant specification, in the only working example of the claimed method, discloses that strains of propionibacteria used in cheesemaking have the recited property. Since the strains of propionibacteria used by Hettinga and in the specification's working example are apparently the same, they would reasonably be expected to have the same properties, including the property of being capable of releasing a physiologically significant amount of nitric oxide in a human or animal digestive tract.

Finally (with respect to claim 13), Appellants argue that the rejection has been overcome by the declaration of Professor Alain Ourry filed July 31, 2001. Appellants rely specifically on ¶ 7 of the declaration, which reads (in relevant part):

> No mention of NO, or nitrogen monoxide, synthesized by these bacteria or even by any other process can be found in the description of this patent. . . . Moreover, it cannot be concluded by any means, from this document that the consumption of cheese produced by the described procedure will release in the digestive tract significant amounts of Propionibacteria, and even so, that they will produce NO.

We do not agree that the Ourry declaration overcomes the rejection. As discussed above, it makes no difference, with respect to anticipation, that Hettinga does not discuss nitric oxide production by the disclosed propionibacteria-containing compositions. Those of ordinary skill in the art would reasonably expect the bacteria to have that capability, and therefore the reference anticipates. It also makes no difference whether those skilled in the art would expect the cheese resulting from Hettinga's process to have the properties recited in the claims: the anticipating

compositions disclosed by the reference are those that are used in the cheesemaking process, not the cheese that ultimately results from that process.

Appellants separately argued claims 14, 15, 16, and 19. See the Appeal Brief, pages 25-26, 32-33, 39-40, and 46-48. In each case, however, they did little more than repeat the same arguments that were made with respect to claim 13: the reference does not expressly describe the limitations of the various claims, "[n]or is it necessary and inevitable that, in the disclosed cheesemaking process," the limitations of the various claims would be met, and the Ourry declaration rebuts the rejection. All of these arguments are sufficiently addressed above.

Only two arguments in the brief require further discussion. With respect to claim 15, Appellants argue that Hettinga does not anticipate because it "does not disclose a food composition which is added to a food product." Appeal Brief, page 32.

This argument is not persuasive. Claim 15, to review, is directed to the composition of claim 13, "wherein said composition is added to a food product." Claim 13 is directed to "[a] composition for use as an absorbable dietary supplement for human and animal consumption." Thus, claim 13 is not limited to "a food composition" and claim 15 does not require adding a food composition to a food product.

With respect to claim 16, Appellants argue that Hettinga "does not disclose a dietary supplement which is a dehydrated preparation, a fermented liquid preparation or an unfermented liquid preparation." Appeal Brief, page 40.

This argument is also not persuasive. As discussed above, Hettinga's propionibacteria-containing inoculum is disclosed to be "G-broth" containing certain strains of propionibacteria at concentrations of more than 10^9 cells per gram. Column 9,

lines 50-52. A broth-based composition would reasonably appear to be a liquid preparation and Appellants have presented no evidence to the contrary. Whether the composition would be better described as a fermented liquid or an unfermented liquid is of no matter: it is a liquid, and all liquids are either fermented or unfermented. Therefore, it reasonably appears to meet the limitations of claim 16.

Summary

Claims 13-16 and 19 reasonably appear to read on the composition disclosed by Hettinga, and Appellants have not shown that the claimed products differ in any way from those in the prior art. We therefore affirm the rejection of claims 13-16 and 19 under 35 U.S.C. § 102(b). Claims 20, 21, 24-26, 29, and 30 fall with claims 13-16 and 19.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Sherman D. Winters)
Administrative Patent Judge)
)
)
) BOARD OF PATENT
Demetra J. Mills)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
Eric Grimes)
Administrative Patent Judge)

Anthony Niewyk
111 East Wayne Street
Suite 800
Fort Wayne, IN 46802

EG/dym